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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/579,403

05/12/2006

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10561.204-US

1367

25908 7590 05/06/2009  
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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

05/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/579,403 | <b>Applicant(s)</b><br>SMITH ET AL. |  |
|                              | <b>Examiner</b><br>Irene Marx        | <b>Art Unit</b><br>1651             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-3, 5-6 and 7-16 is/are pending in the application.  
     4a) Of the above claim(s) 7-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6 and 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

The amendment filed 2/20/09 is acknowledged.

Claims 1-3, 5-6 and 13-16 are being considered on the merits.

Claims 7-12 are withdrawn from consideration as directed to a non-elected invention.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-6 and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is confusing in that it fails to find proper antecedent basis in claim 1 for "the mixture of acidic fungal alpha amylase activity (AFAU) per glucoamylase activity (AGU) (AFAU per AGU...)". No acidic fungal alpha amylase is recited in claim 1.

Claims 13-16 are vague, indefinite and confusing in that any units of activity intended to determine the respective amounts cannot be readily ascertained.

Claims 1-3, 5-6 and 13-16 are incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

### **Response to Arguments**

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

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Applicant argues that the units "AFAU" and "AGU" are clearly defined in the specification on pages 15 and 17-18, respectively.

However, at [0036], the specification states:

The term "carbohydrate-source generating enzymes" includes glucoamylases (being a glucose generators), and beta-amylases and maltogenic amylases (being maltose generators). Other enzymes producing other carbohydrates suitable for the fermenting organism in question is also contemplated according to the invention. A carbohydrate-source generating enzyme is capable of providing energy to the fermenting organism(s) used in the process of the invention and/or may convert the carbohydrate in question directly or indirectly to the desired fermentation product, preferably ethanol. The carbohydrate-source generating enzyme may be mixtures of enzymes falling within the definition. Especially contemplated mixtures are mixtures of at least a glucoamylase and an alpha-amylase, especially an acid amylase, even more preferred a fungal acid alpha-amylase. The ratio between fungal acid alpha-amylase activity (AFAU) per glucoamylase activity (AGU) (AFAU per AGU) may in one embodiment of the invention be at least 0.1, in particular at least 0.16, such as in the range from 0.12 to 0.50.

In addition, at

[0118] the specification states

The Novo Glucoamylase Unit (AGU) is defined as the amount of enzyme, which hydrolyzes 1 micromole maltose per minute under the standard conditions 37.degree. C., pH 4.3, substrate: maltose 23.2 mM, buffer: acetate 0.1 M, reaction time 5 minutes.

While the abbreviations are explained in [0036], the definition at [0118] appears to pertain to specifically to "Novo Glucoamylase Unit (AGU)". The nature of "Novo Glucoamylase" cannot be readily ascertained from the record and is not particularly claim designated. Similarly, the specification states at [0087] "Acid alpha-amylase activity is measured in AFAU (Acid Fungal Alpha-amylase Units), which are determined relative to an enzyme standard." The standard appears to be "The standard used is AMG 300 L (from Novozymes A/S, Denmark, glucoamylase wild-type *Aspergillus niger* G1." However, the test indicated does not clearly set forth the meaning of AFAU in the context of the invention as claimed.

As to the recovery step, the preamble of the claim is directed to the production of a fermentation product. There is nothing in the body of the claim to indicate that a recoverable product is produced. Therefore, the extensive arguments fail to persuade.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5-6 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oda *et al.* taken with Fujii *et al.* taken with Lantero *et al.*, Takeda *et al.*, and Yoshizumi *et al.*.

The claims are directed to the production of any fermentation product with a microorganism in the presence of a glucoamylase or  $\alpha$ -amylase added after the lag phase and producing a product.

Each of Oda *et al.*, Fujii *et al.*, Lantero *et al.*, Takeda., and Yoshizumi *et al.* disclose the production of a fermentation product by culturing a microorganism in the presence of an enzyme such as amylase. See, e.g., Oda *et al.* page 2, col. 2; Fujii *et al.*, page 54, col. 1; Lantero *et al.*, col. 4, lines 57-69; Takeda, col. 5; Yoshizumi *et al.*, Example 2. At least in Oda *et al.*, the enzymes are clearly produced and added to the fermentation medium after the lag phase.

The references differ from the claimed invention in that the timing of the addition of the amylase or glucoamylase is not particularly indicated and in the ratio between the enzymes added. However, one of ordinary skill in the art would have recognized at the time the claimed

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invention was made that the timing of enzyme addition would depend on the extent of the lag phase. It is clear that the lag phase depends not only on the organism fermented but also on the process conditions, such as the fermentation media, as well as on the product desired to be produced. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in adding enzymes at some point after the lag phase, e.g., during the production phase of the process, in order to maintain the fermentation at its maximal yield and avoid possible glucose inhibition, for example.

In addition Lantero *et al.* disclose the use of various fungal alpha-amylases as well as their use mixed with glucoamylase in various amounts (See, e.g., bridging paragraph between col. 2 and 3.)

The process conditions and products discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of production of a fermentation product with a microorganism in the presence of a carbohydrate-source generating enzyme as disclosed by Oda *et al.*, Fujii *et al.*, Lantero *et al.*, Takeda., and Yoshizumi *et al.* by adding a carbohydrate-source generating enzymes such as acid fungal alpha amylase and glucoamylase after the lag phase of the fermenting organism in order to maximize the production of fermentable sugar for the expected benefit of maximizing the yield of valuable products such as ethanol and lactic acid from grains and other vegetable biomass containing starch, for example.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

### **Response to Arguments**

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The arguments by counsel that it is only Applicant's specification that teaches the importance and benefits of delaying the addition of the carbohydrate source generating enzymes

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until after the lag phase of the fermenting organism in a fermentation process has not been substantiated with appropriate evidence. The only showing in the Examples in the as-filed specification is directed to a specific process of culturing yeast in corn mash for the production of ethanol. In this process of production of ethanol, the touted result is that the ratio of glycerol to ethanol is decreased. There is no clear indication as to the precise timing used in the context of "after the lag phase of the fermenting organism" such as by showing a clear growth curve of the yeast cultured. The results in Table 1 show that 100% of "enzyme 20" is added at 0, 8 hrs and 24 hrs. At Table 2 a dosing scheme is shown. It is unclear whether the same or a different enzyme is used. At Table 4 results are shown at 65 and 135 hours comparing glycerol and ethanol production. The relevance of these results to the claimed invention is uncertain.

There is nothing on this record to substantiate arguments regarding advantages for a process as claimed directed to the production of any product with any fermenting organism. From the specification, it is apparent that the production of glycerol, a valuable pharmaceutical intermediate is decreased in the exemplified process. Moreover, the showing appears to be directed to the use of "Glucoamylase SF". It is not apparent that  $\alpha$ -amylase is used in any process. In addition, the unknown product of the instant process is not recovered. Therefore, arguments directed to better or unexpected yield are unpersuasive.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

The references are directed to the production of fermentation products with fermenting organisms and clearly products are produced and recovered. Applicant has not provided evidence to rebut the strong *prima facie* obviousness rejection made.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/  
Primary Examiner  
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